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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership to serve on the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Council). ACBSCT advises the Secretary, acting through the HRSA Administrator, on the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program (Program).

AUTHORITY: The Council was established to implement a statutory requirement of the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109-129). The Council is governed by the Federal Advisory Committee Act, (FACA) as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

DATES: Written nominations for membership on ACBSCT will be received continuously.

ADDRESSES: Nomination packages must be submitted to the Executive Secretary, ACBSCT, Healthcare Systems Bureau, (HSB) HRSA, Room 08W60, 5600 Fishers Lane,

Rockville, Maryland 20857. Federal Express, Airborne, UPS, or any other mail delivery should be addressed to Executive Secretary, ACBSCT, HSB, HRSA, at the above address, or sent via email to: ACBSCTHRSA@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Executive Secretary, ACBSCT, at (301) 443-6839 or email rwalsh@hrsa.gov. A copy of the ACBSCT charter and list of the current membership can be accessed by going to the ACBSCT website at https://bloodcell.transplant.hrsa.gov/about/advisory_council/index.html.

SUPPLEMENTARY INFORMATION: ACBSCT was established pursuant to Public Law 109-129 as amended by Public Law 111-264; 42 U.S.C. 274k; Section 379 of the Public Health Service Act. In accordance with Public Law 92-463, ACBSCT was chartered on December 19, 2006.

ACBSCT, as requested by the Secretary, discusses and makes recommendations regarding the Program. The Council provides a consolidated, comprehensive source of expert, unbiased analysis and recommendations to the Secretary on the latest advances in the science of blood stem cell transplantation. ACBSCT advises, assists, consults, and makes recommendations, at the request of the Secretary, on: 1) broad program policy in areas such as the necessary size and composition of the adult donor pool available through the Program and the composition of the National Cord Blood Inventory; 2) requirements regarding informed consent for cord blood donation; 3) accreditation requirements for cord blood banks; 4) the scientific factors that define a cord blood unit as high quality; 5) public and professional education to encourage the ethical recruitment of genetically diverse donors and ethical donation practices; 6) criteria for selecting the

appropriate blood stem source for transplantation; 7) Program priorities; 8) research priorities; and 9) the scope and design of the Stem Cell Therapeutic Outcomes Database. At the request of the Secretary, ACBSCT also reviews and advises on issues relating more broadly to the field of blood stem cell transplantation, such as regulatory policy pertaining to the compatibility of international regulations, and actions that may be taken by the state and federal governments and public and private insurers to increase donation and access to transplantation. ACBSCT also makes recommendations regarding research on emerging therapies using cells from bone marrow and cord blood. The Council may meet up to three times during the fiscal year.

NOMINATIONS: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on ACBSCT. The Council shall consist of up to 25 members, who are SGEs, and 6 ex-officio, non-voting members. The Secretary appoints ACBSCT SGEs with the expertise needed to fulfill the duties of the Council. HRSA is seeking nominees to serve as members from the following areas: outstanding authorities and representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of bone marrow transplants; recipients of cord blood transplants; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists; hematology and transfusion medicine

researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to ACBSCT will be invited to serve for a term of two years, and are eligible to serve as many as three consecutive 2-year terms. SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACBSCT meetings and/or conducting other business on behalf of the Council, as authorized by 5 U.S.C. § 5703 of the Federal Travel Regulation for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual being nominated for consideration: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (i.e., what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of ACBSCT), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee; (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted; and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS endeavors to ensure that ACBSCT membership is balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the

basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required for HRSA ethics officials to determine whether there is a conflict between the SGE's public duties as a member of ACBSCT and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

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